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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,473	04/06/2005	Seiji Yamamoto	GRT/423-70	4977
<div>23117 7590 11/15/2007 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203</div>				
<div>EXAMINER KETTER, JAMES S</div>				
<div>ART UNIT PAPER NUMBER</div> <div>1636</div>				
<div>MAIL DATE DELIVERY MODE</div> <div>11/15/2007 PAPER</div>				

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/530,473

Applicant(s)

YAMAMOTO ET AL.

Examiner

James S. Ketter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6,7,9,12-17,22 and 23 is/are rejected.
- 7) ☒ Claim(s) 3-5,8,10,11 and 18-21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>(3)</u> . | 6) <input type="checkbox"/> Other: _____ |

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Applicant's election with traverse of Paramyxovirus family in the reply filed on 21 June 2007 is acknowledged. The traversal is on the ground(s) that examination of all viruses and virus families would not be a burden, and that the independent claims are generic. This is not found persuasive because, with respect to burden, each family and its individual members represents a separate search. With respect to the independent claims, the invention is properly restricted under the controlling PCT rules as set forth in the restriction requirement.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-23 are objected to because of the following informalities: The instant claims are drawn in part to non-elected subject matter. Appropriate correction is required.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 6, 7, 9 and 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kumar et al. (U, newly cited) in view of Bally et al. (V, newly cited).

Claim 1 is drawn to a pharmaceutical preparation comprising, as an active ingredient, a virus envelope vector having a chemotherapeutic agent incorporated therein. Claim 2 specifies that the chemotherapeutic agent is a cancerocidal agent, an anticancer agent, or an antitumor agent. Claim 6 specifies that the virus is derived from a virus belonging to a family selected from the group consisting of the retrovirus family, togavirus family, coronavirus family, flavivirus family, paramyxovirus family, orthomyxovirus family, bunyavirus family, rhabdovirus family, poxvirus family, herpes virus family, baculovirus family and hepadnavirus family. Claim 7 specifies that the virus is a member selected from the group consisting of Sendai virus, retrovirus, adenovirus, adeno-associated virus, herpes virus, vaccinia virus, poxvirus and influenza virus. Claim 9 specifies that the pharmaceutical preparation is an injection. Claim 12 specifies that the pharmaceutical preparation is a therapeutic agent for solid cancer. Claim 13 specifies that the pharmaceutical preparation is for a solid tumor selected from the group consisting of lung cancer, breast cancer, digestive organ cancer, head and neck cancer, gynecologic cancer, urologic cancers, soft tissue and bone sarcoma, malignant lymphoma and cancer of unknown primary. Claim 14 specifies that the digestive organ cancer is selected from the group consisting of stomach cancer, colon cancer and esophagus cancer. Claim 15 specifies that the pharmaceutical preparation is selected from the group consisting of upper jaw cancer, tongue cancer, lip cancer, pharynx cancer, larynx cancer and oral cavity cancer. Claim 16

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specifies that the pharmaceutical preparation is selected from the group consisting of uterus cancer, ovarian cancer and uterine cervical cancer. Claim 17 specifies that the pharmaceutical preparation is for prostate cancer.

Kumar et al teaches, e.g., as summarized in the Abstract, the fusion of Sendai virus envelopes loaded with lysozyme with teratocarcinoma cells. At page 20, right-hand column, first full paragraph, it is suggested that the virosomes described therein could be used to carry anticancer drugs. Kumar et al. differs from the claimed invention in not actually disclosing the combination of any particular cancer drug with the Sendai-derived virosome.

Bally et al. teaches, e.g., at the first paragraph of column 8, that liposomes may be used to encapsulate anticancer agents, including bleomycin, cisplatin, fluorouracil and cytarabine.

It would have been obvious to one of ordinary skill in the art to have selected one of the anticancer agents taught by Bally et al. as useful in a liposome for loading and use in the virosome of Kumar et al. Kumar et al. already suggested the loading of a Sendai-derived virosome envelope with an anticancer drug. The drugs taught by Bally et al. were known in the art to be useful against cancer, and one of ordinary skill in the art would have expected that any of them could be loaded into a virosome as readily as into a liposome, which are chemically and structurally similar. With respect to the various recited tumor types targeted, these merely represent intended uses. The pharmaceutical resulting from the combination of the references could have been used against any tumor type.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims recite "radiations". However, since "radiation" in the singular is often used in a collective sense, i.e., all frequencies or particles collectively referred to as "radiation", it is not clear if the plural is meant to convey a specific meaning, e.g., multiple frequencies or multiple doses. Clarification is requested.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James S. Ketter whose telephone number is 571-272-0770. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JSK
1 September 2007



JAMES KETTER
PRIMARY EXAMINER